

Notice of Allowability

Application No.

10/801,469

Examiner

Robert Shiao, Ph.D.

Applicant(s)

QIAO ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on 12 October, 2006.
2. ☒ The allowed claim(s) is/are 1-10, 13, and 15-22, now are 1-19.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

1. This application claims benefit of the provisional applications:
60/455,733 with a filing date 03/18/2003; and
60/508,232 with a filing date 10/02/2003.
2. The applicant's petition filed under 37 CFR 1.48(a) and an oath or declaration, dated 03/30/2005, for correction of inventorship for the instant application, is acknowledged. The inventorship has been corrected, and the inventors are:
Jennifer X. Qiao, Tammy C. Wang, Gren Z. Wang and Timur Gungor.
3. Amendment of claims 1-9, cancellation of claim 14, and addition of claims 15-22 in the amendment filed on October 12, 2006, is acknowledged. Claims 1-13 and 15-22 are pending in the application. No new matter is found. Since the newly added claims 15-22 are commensurate with the scope of the invention, claims 1-13 and 15-22 are prosecuted in the case.

Responses to Amendment/Arguments

4. Applicant's arguments regarding the rejection of claims 1-10 under 35 U.S.C. 102(a) or 102(e) over Pinto et al. '208, filed on October 12, 2006, have been fully considered and they are persuasive. Pinto et al. compounds have not been claimed in the instant application. The rejection of claims 1-10 under 35 U.S.C. 102(a) or 102(e) over Pinto et al. '208 has been withdrawn herein.
5. Applicant's arguments regarding the rejection of claims 1-10 under 35 U.S.C. 103(a) over Pinto et al. '208 or '391, or over Jacobson et al. '872, filed on

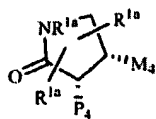
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October 12, 2006, have been fully considered and they are persuasive. Applicants submit that Pinto et al. '208 or '391, and Jacobson et al. '872, are disqualified under 35 U.S.C. 103(c) as prior art against the instant application as the subject matter of Pinto et al. or Jacobson et al. and the presently claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." Therefore, the rejection of claims 1-10 under 35 U.S.C. 103(a) over Pinto et al. '208 or '391, or over Jacobson et al. '872 has been withdrawn herein.

6. Since the provisional rejection of claims 1-10 under obviousness-type double patenting over the co-pending application No. 11/198,801 or 10/952,204 is the only remaining rejection, therefore the provisional rejection of claims 1-10 under obviousness-type double patenting has been withdrawn herein.

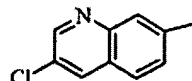
EXAMINER'S AMENDMENT

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Jing G. Sun on November 27, 2006. The application has been amended as follows:



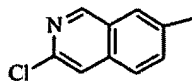
In claim 1, line 6, after “

--and--



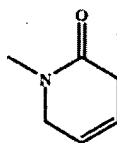
In claim 2, page 22, line 8, after “

--and--



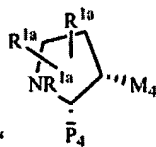
In claim 3, page 31, line 5, after “

--and--



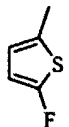
In claim 3, page 33, line 1, after “

--and--



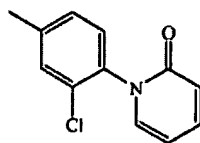
In claim 4, page 37, line 3, after “

--and--



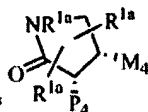
In claim 4, page 41, line 3, after “

--and--



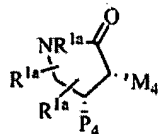
In claim 4, page 45, line 3, after “

--and--



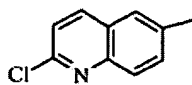
In claim 5, page 47, line 1, after “

--and--



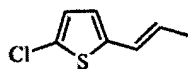
In claim 5, page 47, line 2, after “

--;--



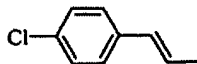
In claim 5, page 49, line 1, after “

--and--



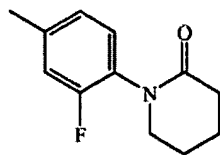
In claim 5, page 49, line 7, after “

--and--



In claim 5, page 49, line 7, after “

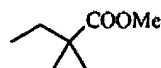
--;--



In claim 5, page 50, line 4, after “

”, insert

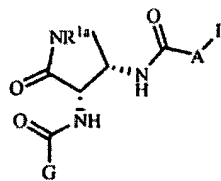
--and--



In claim 5, page 52, line 3, after “

”, insert

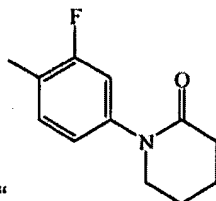
--and--



In claim 6, page 53, line 1, after “

”, insert

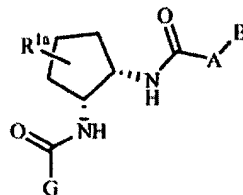
--and--



In claim 6, page 53, line 5, after “

”, insert

--and--



In claim 7, page 53, line 3, after “

”, insert

--and--

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In claim 13, line 1, after "A method", delete "according to Claim 11", and insert --for treating a thromboembolic disorder, comprising: administering to a patient in need thereof a therapeutically effective amount of a compound of Claim 1 or a pharmaceutically acceptable salt form thereof--

Delete claims 11-12.

Reasons for allowance

8. The following is an examiner's statement of reasons for allowance:

Claims 1-10 and 15-22 are allowable. Claim 13 is previously withdrawn from consideration as a result of a restriction requirement, require all the limitations of an allowable claim. Pursuant to the procedures set forth in MPEP § 821.04(a), **the restriction requirement among inventions groups, as set forth in the Office action mailed on April 13, 2006, is hereby withdrawn** and claim 13 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 1-10, 13 and 15-22 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to lactam-containing cyclic diamines and derivatives as factor Xa inhibitors. The closest prior art is Lam et al. US 6,339,099, which discloses guanidine mimics as factor Xa inhibitors. The difference between the reference and instant claims is that instant claimed compounds/compositions have not been found. A suggestion for modification of above reference to obtain the instant compounds/compositions and methods of use has not been found. Claims 1-10, 13 and 15-22 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information

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for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.S.

Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

Joseph K. McKane

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626

November 28, 2006